

United States Nuclear Regulatory Commission
Preliminary Proposed Rule Language
Part 35 of Title 10 of the *Code of Federal Regulations* (10 CFR)
[NRC-2022-0218; RIN 3150-AK91]

This preliminary proposed rule language does not represent a final NRC staff position, nor has it been reviewed by the Commission. Therefore, the preliminary proposed rule language may undergo significant revision during the rulemaking process. The preliminary proposed rule language would amend the following sections as indicated by text in **red**:

§ 35.2 Definitions.

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Extravasation means the leakage of a radiopharmaceutical from the blood vessel into the surrounding tissue.

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Medical attention means any techniques used to reduce the chance, severity, or symptoms of a suspected radiation injury.

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Suspected radiation injury means a potential or observable deterministic health effect to the area around an injection site that can be attributed to radiation.

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§ 35.42 Procedures for evaluating and reporting extravasations.

(a) For any administration in which an extravasation can occur, the licensee must develop, implement, and maintain written procedures to provide high confidence that an

extravasation that requires medical attention for a suspected radiation injury will be detected and reported in a timely manner and in accordance with § 35.3045.

(b) The written procedures required by paragraph (a) of this section must address how the licensee determines that an extravasation meets the criteria in § 35.3045(a)(3) for a medical event.

(c) A licensee must retain a copy of the procedures required under paragraph (a) in accordance with § 35.2042.

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§ 35.2042 Records for procedures for evaluating and reporting extravasations.

A licensee must retain a copy of the procedures required by § 35.42(a) for the duration of the license.

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§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which –

(1) * * *

(2) * * *

(3) The administration of byproduct material results in an extravasation that requires medical attention for a suspected radiation injury.

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